DETAILED ACTION

Claims 1 and 5-29 are presented for examination.

Applicant's Amendment filed December 30, 2009 has been received and entered into the present application.

Applicant's Information Disclosure Statements (IDS) filed December 30, 2009 (two pages) and February 17, 2010 (two pages) have each been received and entered into the present application. As reflected by the attached, completed copies of form PTO/SB/08A (four pages total), the Examiner has considered the cited references.

Claims 1 and 5-29 are pending. Claims 7-19 and 21 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 25-29 are newly added. Claims 1, 20 and 22-23 are amended. Claims 1, 5-6, 20 and 22-29 are under examination.

Applicant's arguments, filed December 30, 2009, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Objection to the Claims

Claims 5-6 remain objected to as being dependent from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Instant claim 25 is directed to a composition for improving the bioavailability of a drug comprising at least one poorly bioavailable drug dissolved in an effective amount of menthol, wherein the drug is diazepam, danazole, progesterone, estradiol, estrone, proquazone, and ketoprofen; the effective amount of menthol is 20% to 99% by weight of the composition; and the composition is suitable for oral administration.

In particular, claim 25 as presently written fails to clearly, precisely or deliberately set forth those poorly bioavailable drug(s) that may be contained within the claimed composition. Specifically, the phrase "at least one poorly bioavailable drug" indicates that any one drug or combinations of the listed poorly bioavailable drugs listed in the claim may be used in the claimed composition. However, this directly conflicts with the list of poorly bioavailable drugs recited in the claim, which requires the incorporated drug component to be "diazepam, danazole, progesterone, estradiol, estrone, proquazone, and ketoprofen", i.e., all seven listed drugs, which does not provide for the use of "at least one" drug thereof. As a result of this ambiguity in the claims, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

For the purposes of examination, instant claim 25 will be interpreted to read on a composition that comprises at least one of the drugs recited in the claim.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 20 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (WO 01/89485; 2001).

Lee et al. teaches tablets that have enhanced strength and rapid disintegration rate in the oral cavity that comprising an active ingredient, a sublimable substance suitable for oral administration and a pharmaceutically acceptable additive, wherein the additive may be, e.g., a saccharide, buffer, surfactant, poly(ethylene glycol), excipient and lubricant (abstract; p.3, l.5-10). Lee et al. further teaches that the active ingredient may be selected from any pharmacologically active ingredients that are amenable to oral administration, including preferred compounds such as, *inter alia*, ketoprofen, nifedipine, or verapamil (p.3, l.13-p.4, l.4), wherein the active ingredient is used in an amount of 0.5-80% by weight, preferably 1-70% by weight, of the composition (p.4, l.5-6), and the sublimable substance may be selected from any substance that causes no harmful effects when administered orally, including the preferred substance menthol, wherein the sublimable substance is used in an amount of 5-50% by weight, preferably 10-40% by weight, of the composition (p.4, l.9-30).

Though it is noted that the amount of sublimable substance (i.e., menthol) used in the composition of Lee et al. (i.e., 5-50% by weight of the composition) is outside "about 60%) as instantly

claimed (claim 24), this teaching of 5-50% menthol by total weight of the composition is understood to meet Applicant's claimed amount of menthol of "about 60%" (claim 24) because the term "about" as used in instant claim 24 permits some tolerance both above and below the recited endpoint absent an explicit definition of the degree of variation intended to be encompassed by the term. Where close prior art exists (such as, in this case, Lee et al.), the burden is on Applicant to establish that the term "about" as used in the instant claims is sufficiently clear to avoid such art. In the instant case, Applicant has failed to provide a definition of the term "about" in the instant specification, such that there is no indication or hint as to what amount of variation above or below the recited amount would constitute infringement of the instant claims. There is nothing in the specification, prosecution history or prior art that provides any indication as to what amount of variation is tolerated by the term "about". Absent such information, and further in view of what is actually disclosed by Lee et al. (i.e., 5-50% menthol by total weight of the composition), this teaching of Lee et al. is understood to meet Applicant's claimed amount of "about 60%" (claim 24), absent factual evidence to the contrary, and further absent any clear indication in the specification or claims that an amount of 5-50% would not be encompassed by the variation in and around the endpoint of "about 60%" (claim 24).

Regarding Applicant's limitations directed to (1) wherein the average area under the blood or plasma concentration versus time curve (AUC) of said composition is at least 5% more than the average AUC of a non-menthol containing formulation of the same drug (claims 20 or 26), (2) wherein the average AUC of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claims 22 or 27) or (3) wherein the average AUC of said composition is at least 15% more than the average AUC of a non-menthol containing formulation (claims 23 or 28), the pharmaceutical composition of Lee et al. comprises the identical active agents in an identical physical structure (e.g., a composition suitable for oral administration) in identical amounts to that instantly claimed. Therefore, the composition of Lee et al. must necessarily possess the same AUC characteristics

(as defined in instant claims 20, 22-23 or 26-28) as that presently claimed whether recognized by the patentee or nor because products of identical chemical composition cannot exert mutually exclusive properties when prepared or used in the same manner under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same active agents, same physical structure, same amounts, etc.), the properties that Applicant discloses and/or claims must necessarily be present. See MPEP §2112.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is, in fact, inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though Lee et al. may not expressly teach the average AUC of the disclosed composition versus the average AUC of the disclosed composition without the menthol component, the prior art to Lee et al. contains the same active agents as that presently claimed in the same physical structure and in the same amounts, and, therefore, the resultant AUC properties must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, Lee et al. does not possess these same claimed characteristics.

Lee et al. fails to teach the use of the sublimable substance menthol in an amount of 60-90% by weight of the composition (claim 29).

The determination of the optimal amount(s) of the sublimable substance menthol as used in the rapidly disintegrating tablets of Lee et al. would have been a matter well within the skill of the artisan at the time of the invention and would not have been outside the realm of knowledge generally available to the skilled artisan. Since Lee et al. teaches that it is the function of the sublimable substance to generate pores inside the tablet that allows for rapid disintegration due to its porosity (Lee et al., p.4, l.10-15), one of ordinary skill in the art at the time of the invention would have found it *prima facie* to modify the amounts based upon various factors, including, but not limited to, the age and medical condition of the patient (i.e., which would impact the ability of the patient to swallow oral tablets that do not rapidly disintegrate), pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination, as well as the desired time to complete disintegration. Thus, the concentration(s) that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific concentration of menthol is not seen to be inconsistent with that which would have been readily determined by one of skill in the art from the teachings of Lee et al.

In addition, the concentration of the active ingredient(s) is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). Please see MPEP §2144.05[R-2](II)(A) and *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ("[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

ranges by routine experimentation.").

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dugger III (U.S. Patent No. 6,110,486; 2000) in view of PDR for Herbal Medicines (p.628-631; 2004).

All cited references are already of record.

Dugger teaches buccal spray compositions for transmucosal administration of a pharmaceutically active compound soluble in a pharmacologically acceptable polar solvent comprising polar solvent in an amount of 75-99.8% by weight of the total composition; active compound in an amount of 1-20% by weight of the total composition; and also containing, a flavoring agent in an amount of 0.5-5% (col.2, l.5-14), as well as soft bite gelatin capsules for transmucosal administration of a pharmacologically active compound, at least partially soluble in a pharmacologically acceptable polar solvent comprising polar solvent in an amount of 40-99.8% by weight of the total composition, emulsifier in an amount of 0-20% by weight of the total composition; active compound in an amount of 0.03-35% and also comprising a flavoring agent in an amount of 0.05-60% by weight of the total composition (col.2, l.15-23). Dugger teaches that preferred flavoring agents include, *inter alia*, oil of peppermint (col.3, l.66-col.4, l.2) and the active compound may be, *inter alia*, progesterone (col.4, l.22-23). Exemplary formulations are disclosed, including a progesterone soft bite capsule as described in Example 9, which contains 85% polyethylene glycol, 7.89% glycerin, 5.0% lecithin, 1.11% progesterone and 1.0% oil of peppermint (Ex.9, col.8, l.24-50), and further teaches that the flavoring agent may be included in an amount of 0.05-5% (col.8, l.30-35). Dugger teaches that the disclosed compositions provide the biologically active compound for rapid absorption through the oral mucosa (i.e., which is understood as a teaching that the composition is clearly "suitable for oral administration" as instantly claimed).

PDR for Herbal Medicines (p.628-631; 2004) is cited for its teaching that peppermint oil contains 35-45% menthol (col.2, para.4, p.628). Citation to this reference is made in accordance with MPEP

§2131.01, which states that it is proper to rely upon a secondary reference for a rejection under 35 U.S.C. 102 provided that the additional reference is relied upon to demonstrate that a characteristic or property not disclosed by the primary reference is, in fact, inherent.

Note that the exemplary progesterone formulation contains 1% peppermint oil by weight of the total composition or suggests that the flavoring agent (which, in this exemplary formulation, is peppermint oil) may be used in an amount of 0.05-5% for this disclosed example (Ex.9, col.8, l.25-50), Dugger explicitly teaches that the flavoring agent, including, *inter alia*, peppermint oil, is used in an amount of 0.05-60% by weight of the total composition when the composition is in the form of a soft bite gelatin capsule comprising polar solvent, emulsifier and the active compound (see, e.g., p.2, l.15-22). Such disclosure is an unambiguous teaching that the amount of the flavoring agent of this progesterone soft bite capsule may be varied within the disclosed parameters of 0.05-60% by weight of the total composition and still arrive at a product contemplated and within the scope of the invention disclosed by Dugger. This is because it is evident that the progesterone soft bite capsule of Example 9 (discussed *supra*) is employing a narrower range of flavoring agent of the broader range disclosed for the purposes of providing an exemplary formulation, but the fact that Dugger discloses a broader range of possible amounts of flavoring agent that may be used (i.e., in this case, peppermint oil) supports the interpretation that Dugger contemplated the substantial interchangeability of the amount of flavoring agent while still preserving the advantageous properties of the invention such that the amounts of the components (i.e., in this particular case, the amount of flavoring agent) may be varied therein the disclosed parameters and still form a preparation within the scope of the invention, absent factual evidence to the contrary.

Further note that, if Dugger was to provide a progesterone formulation using the elements of the formulation described in Example 9 but with a greater amount of the flavoring agent used therein (i.e., peppermint oil), such as 0.05-60% as disclosed at col.2, l.15-22, such a range of peppermint oil would then contain between 0.0175% menthol [(0.05/100) x (35/100) x 100 = 0.0175%] and 27% menthol

[(60/100) x (45/100) x 100 = 27%], which clearly overlaps with the amounts instantly claimed in, e.g., instant claim 25.

Regarding Applicant's limitations directed to (1) wherein the average area under the blood or plasma concentration versus time curve (AUC) of said composition is at least 5% more than the average AUC of a non-menthol containing formulation of the same drug (claim 26), (2) wherein the average AUC of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claim 27) or (3) wherein the average AUC of said composition is at least 15% more than the average AUC of a non-menthol containing formulation (claim 28), the pharmaceutical composition of Dugger comprises the identical active agents in an identical physical structure (e.g., a composition suitable for oral administration) in identical amounts to that instantly claimed. Therefore, the composition of Dugger must necessarily possess the same AUC characteristics (as defined in instant claims 26-28) as that presently claimed whether recognized by the patentee or nor because products of identical chemical composition cannot exert mutually exclusive properties when prepared or used in the same manner under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same active agents, same physical structure, same amounts, etc.), the properties that Applicant discloses and/or claims must necessarily be present. See MPEP §2112.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is, in fact, inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003);

see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though Dugger may not expressly teach the average AUC of the disclosed composition versus the average AUC of the disclosed composition without the menthol component, the prior art to Dugger contains the same active agents as that presently claimed in the same physical structure and in the same amounts, and, therefore, the resultant AUC properties must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, Dugger does not possess these same claimed characteristics.

Response to Applicant's Arguments

Applicant traverse the previous application of Dugger under 35 U.S.C. 103(a), stating that Dugger fails to disclose the use of peppermint oil in an amount higher than 1.5% in capsule formulations and also fails to disclose the use of flavoring agent in an amount higher than 5% when disclosing formulations of estradiol or progesterone (Ex.6-13). Applicant concludes that Dugger fails to provide any motivation to use peppermint oil in an amount much higher than 1.5% or 5%. Applicant further states that, if one were to use a greater amount of flavoring agent in the formulation of Ex.9, only 24.7% of the composition could be used for emulsifier/wetting agents and the flavoring agent and, therefore, would contain less menthol than what is now required by the instant claims.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant argues that Dugger fails to provide any motivation to use peppermint oil in an amount higher than 1.5% and 5% and relies upon the Examples to support this position. This is unpersuasive. The fact that Dugger describes exemplary embodiments according to the invention that contain, e.g., progesterone, with a low amount of flavoring agent (i.e., in this case, peppermint oil) does

not constitute a teaching away from the disclosure that both the active drug and the flavoring agent may be varied within the parameters and ranges taught in the reference to arrive at other embodiments of the invention. The fact that Dugger may have elected to exemplify an embodiment of the disclosure wherein the amount of flavoring agent used was on the lower end of the disclosed range of 0.05-60% by weight of the composition fails to teach away from using other amounts of flavoring agent within the disclosed range, including, e.g., 60% flavoring agent by weight of the composition. A preferred or exemplified embodiment (in this case, Examples 6-13) does not constitute a teaching away from other embodiments disclosed or suggested within the four corners of the reference. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Please see MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments…Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." Thus, the fact that another embodiment that differs from the subject matter relied upon as being relevant to the instant claims may be exemplified or preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates, compositions that contain larger amounts of flavoring agent (i.e., peppermint oil) and, thus, menthol. Moreover, Applicant is reminded that there is no legal requirement that a reference *must exemplify* a particular embodiment in order to constitute a teaching of the same. A reference will constitute a teaching so long as the disclosure clearly describes and enables such an embodiment and, in the present case, such description is clearly found in Dugger.

Applicant is again reminded that Dugger explicitly teaches that the flavoring agent, including, *inter alia*, peppermint oil, is used in an amount of 0.05-60% by weight of the total composition when the composition is in the form of a soft bite gelatin capsule comprising polar solvent, emulsifier and the

active compound (see, e.g., p.2, l.15-22). Such disclosure is an unambiguous teaching that the amount of the flavoring agent of this progesterone soft bite capsule may be varied within the disclosed parameters of 0.05-60% by weight of the total composition and still arrive at a product contemplated and within the scope of the invention disclosed by Dugger. This is because it is evident that the progesterone soft bite capsule of Example 9 (discussed *supra*) is employing a narrower range of flavoring agent of the broader range disclosed for the purposes of providing an exemplary formulation, but the fact that Dugger discloses a broader range of possible amounts of flavoring agent that may be used (i.e., in this case, peppermint oil) supports the interpretation that Dugger contemplated the substantial interchangeability of the amount of flavoring agent while still preserving the advantageous properties of the invention such that the amounts of the components (i.e., in this particular case, the amount of flavoring agent) may be varied therein the disclosed parameters and still form a preparation within the scope of the invention, absent factual evidence to the contrary.

Secondly, Applicant argues that, if one were to use a greater amount of flavoring agent in the formulation of Ex.9, only 24.7% of the composition could be used for emulsifier/wetting agents and the flavoring agent and, therefore, would contain less menthol than what is now required by the instant claims. This is also unpersuasive. Applicant is attempting to literally incorporate a greater amount of flavoring agent into the formulation disclosed in Ex.9 without considering the broader teachings of the reference as a whole. Ex.9 provides a progesterone formulation that contains polyethylene glycol, glycerin, lecithin, progesterone and oil of peppermint, each component of which is described generically in the broader disclosure as a selection from a list of possible choices, each with a disclosed range of amounts that provide compositions according to the objective(s) of the invention. As such, each of these parameters may be varied within the limits disclosed by the reference to arrive at other embodiments of the invention, wherein the actual elements of the composition may be the same as that disclosed in Ex.9 but the amounts may be varied within the bounds of the disclosure. Thus, the *concept* of providing a

progesterone formulation containing similar components to those described in Ex.9, but with differing amounts of these active components, is still clearly suggested by the reference. As a result, notwithstanding the fact that the amounts of the polyethylene glycol, glycerin, lecithin and progesterone would be varied as well, Dugger clearly provides a suggestion to use up to 60% by weight flavoring agent, which, in this particular example would be peppermint oil. As calculated *supra* and in the previous Office Action, such an amount of peppermint oil would clearly provide for menthol in an amount of 0.0175%-27% by weight of the composition, which clearly overlaps with the amounts instantly claimed in, e.g., claim 25. In view of these teachings, a complete consideration of the full scope of the teachings contained within Dugger clearly demonstrates that Applicant's interpretation of the reference as only providing for, at most, 8.645-12.33% menthol when considering the formulation disclosed in Ex.9 is unduly narrow and fails to establish nonobviousness of the instant claims over the disclosure to Dugger.

For these reasons *supra*, rejection of claims 25-28 remains proper.

Conclusion

Rejection of claims 1, 20 and 22-29 is proper.

Claims 5-6 are objected to for depending from a rejected base claim.

Claims 7-19 and 21 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-**

MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

April 24, 2010

/Ardin Marschel/
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